

## **REMARKS**

Claims 18, 20, 23-26 and 31-36 are pending in this application. By this Amendment, claims 18 and 20 are amended and new claim 36 is added. No new matter is added.

### **Section 112 Rejection**

The Office Action rejects claims 18, 20, 23-26 and 31-35 under 35 U.S.C. § 112, first paragraph, as not being sufficiently described in the specification. This rejection is traversed.

The Patent Office asserts that the specification does not provide support for method claims since the original claims were "Use" claims. However, Applicant respectfully submits that it is clear that the originally filed specification and claims clearly disclose "the treatment of chronic inflammations" (see original claim 1) where the inflammation can be "associated with an immune disease" (original claim 2) that can be "an auto-immune disease" (claim 3) that can be "rheumatoid arthritis" (claim 4). The originally filed specification and claims clearly disclose "treatment of symptoms associated with rheumatoid arthritis" (claim 5) that can be "morning stiffness, painful and swollen joints, loss of grip strength and pain" (claim 6).

An exemplary method of treating and ameliorating is described on pages 5-13 of the specification. In the treatment method, "[r]ecombinant human Erythropoietin...was administered three times a week at a dose of 240 units/kg subcutaneously at the right upper leg for 6 weeks" (see page 6, lines 15-19). In the method described, a "decrease in [erythrocyte sedimentation rate] was found in all patients...[and] a significant

decrease in the [C-reactive protein] levels was observed” (see page 7, lines 19-31). Also in the treatment method described, “painscore” and “morningstiffness showed a decrease (see page 7, line 34 to page 8, line 3), and gripstrength and swollen joints “showed a continuous tendency towards improvement which lasted during, and also after, the treatment period” (page 8, lines 6-13).

Thus, Applicant respectfully submits that the originally filed specification and claims provides clear support for “A method of treating morning stiffness, loss of grip strength, painful joints, or swollen joints” as well as for “A method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level.”

For at least the above reasons, reconsideration and withdrawal of the rejection of claims 18, 20, 23-26 and 31-35 under 35 U.S.C. § 112, first paragraph, are respectfully requested.

### **Section 102 Rejections**

The Office Action rejects claims 18, 20, 23-26 and 32-35 under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Toshihide et al. The Office Action rejects claims 18, 20, 23-26 and 31-35 under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Pettersson et al. These rejections are traversed as they may apply to the above-amended claims.

Applicant have previously noted that Peterson et al. teach that the Pettersson et al. treatment with rHuEPO resulted in “no significant change in our patients’ joint status or in their [erythrocyte sedimentation rate] and [C-reactive protein] values” (emphases

added). Thus, since Pettersson et al. discloses no significant change in these valves, Applicant continues to believe that Pettersson et al. can not anticipate the present claims, which require treatment (claim 18) and amelioration (claim 20) of symptoms left untreated by Pettersson et al.

As Applicant has also previously submitted, Toshihide et al. nowhere teach the treatment (claim 18) and amelioration (claim 20) of the symptoms that Pettersson et al. clearly teach are not treated by rHuEPO. Thus, Applicant continues to believe that Toshihide et al. also can not anticipate the present claims.

Additionally, since steps of treating or ameliorating certain symptoms are not taught or suggested (but are taught against) by Pettersson et al. and Toshihide et al, Applicant continues to believe that the present claims would not have been obvious over either reference.

Applicant has also previously explained that the claims defining the method using "consisting of" language excludes patients also having iron added, as in Pettersson et al., and having blood collected, as in Toshihide et al.

However, in order to expedite prosecution of this application, Applicant has amended claims 18 and 20 to further define that the patient has not been treated with iron. Applicant notes that this limitation is supported on page 6, lines 6-7 of the present specification, where it is stated that "[p]atients treated previously with iron...were excluded." Applicants respectfully submit that this limitation even more clearly overcomes the Pettersson et al. reference.

For at least the above reasons, reconsideration and withdrawal of the rejections of claims 18, 20, 23-26 and 32-35 and of claims 18, 20, 23-26 and 31-35 under 35 U.S.C. § 102(b) or 35 U.S.C. § 103(a) are respectfully requested.

**Conclusion**

Applicant respectfully submits that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event this paper is not considered to be timely filed, Applicant respectfully petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300, making reference to Attorney Docket No. 108214-07002.

Respectfully submitted,



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